Canadian Grain Commission Commission canadienne des grains

Canada

Canadian Grain Commission

Quality System Procedure

Conducting a Food Safety/IP Quality Management System Audit

CGC QSP 2.3.1

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CONTENTS

REVIEW

This Canadian Grain Commission (CGC) Quality System Procedure (QSP) is subject to annual review. Amendments will be issued to ensure the QSP continues to meet current needs.

REVISION HISTORY

Revisions to this procedure will be given a consecutive number and will be dated.

Please ensure that all revisions are inserted, obsolete pages removed, and the record below is completed.

Revision No.	Revision Content and Pages	Entered by:	Date:
Initial release	Supersedes CGC IP-QSP 2.3.0	J. Sutherland	May 20, 2009
Revision 1	Format and wording changes to entire document	M. Stoughton	August 1, 2012
Revision 2	Format and wording changes to entire document	E. Bernardin	November 1, 2012
Revision 3	Format and wording changes to entire document.	E. Bernardin	April 1, 2017
	p. 3—added CIPRS objectives to Section 3.0 – Audits.	E. Bernardin	April 1, 2017
	p. 12—Section 6.1—clarified examples of minor non-conformances	E. Bernardin	April 1, 2017
	Pages 20-22—Appendix I—made changes to traceability audit information	E. Bernardin	April 1, 2017
	p. 29—added Appendix VII on Reduced CGC HACCP Audit Model	E. Bernardin	April 1, 2017

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ACRONYMS

ASP	Accredited Service Provider
CAR	Corrective Action Request
CCP	Critical Control Point
CGC	Canadian Grain Commission
CL	Control Limit
FSQMS	Food Safety Quality Management System
HACCP	Hazard Analysis Critical Control Point
IP	Identity Preserved / Identity Preservation
PVA	Process Verification and Accreditation Office
QSP	Quality System Procedure

1.0 INTRODUCTION

The Canadian Grain Commission Food Safety and Identity Preserved Quality Management System standard (CGC FSIP-STAN 1.1.0) sets out the requirements grain companies must meet if they wish to:

a) have their Identity Preserved Quality Management System certified under the Canadian Identity Preserved Recognition System Program (CIPRS); or

b) have their Food Safety and Identity Preserved Quality Management System certified under the Canadian Identity Preserved Recognition System Plus HACCP Program (CIPRS+ HACCP); or

c) have their HACCP-based Food Safety and Quality Management System certified under the CGC HACCP Program.

This audit procedure provides instruction to CGC Accredited Service Providers (ASP) for the planning, implementation and follow-up of audits against the standard for the above three programs.

The audit requirements common to all three programs are listed first under each heading and are not shaded.

Additional requirements for identity preservation (CIPRS) are presented with this shading.

Additional requirements for a HACCP-based food safety system (CIPRS+ HACCP or CGC HACCP) are presented with this shading.

CGC ASPs conduct audits to ensure that a company's program meets the requirements of the CGC FSIP-STAN 1.1.0 for the type of certification they are seeking. A documentation review is completed, followed by an on-site audit to seek objective evidence to verify that the system is being implemented as documented.

ASPs then submit an audit report to the Process Verification and Accreditation Office (PVA) where a technical review is conducted and a decision made on whether the company's system meets the appropriate requirements of CGC FSIP-STAN 1.1.0. If the decision is favourable, certification is issued and is valid for a period of three (3) years, provided the annual system assessments indicate continued conformity of the company's system.

This audit procedure provides ASP auditors with instruction on how to conduct these assessments and what objective evidence should be collected to demonstrate that proper implementation has occurred.

1.1 References

CGC FSIP-STAN 1.1.0 - CGC Food Safety & Identity Preserved Quality Management System Standard

CGC QSP 1.1.0 - Certification of an Identity Preserved and/or HACCP-Based Food Safety Program (CIPRS, CIPRS+HACCP, CGC HACCP)

CGC QSP 2.1.0 - Accreditation and Monitoring of CGC Accredited Service Providers

ISO 19011:2002 - Guidelines for quality and/or environmental management systems auditing

Codex Alimentarius Commission – General principles of food hygiene, CAC/RCP 1 – 1969, Rev. 4-2003, including "Annex on Hazard Analysis Critical Control Point (HACCP) System and Guidelines for its Application"

CGC Prerequisite Programs - Canadian Grain Commission Generic Good Operating Practices for Grains, Oilseeds, and Pulses Grain Handling and Processing Facilities

CGC Generic HACCP Plan for the Handling of Grains, Oilseeds and Pulses

1.2 Definitions

Audit Report – a report submitted by the ASPs to the PVA detailing the findings of their audits of companies' food safety/IP programs.

Client – a company that has applied for certification of its food safety and/or IP program under CIPRS, CIPRS+ HACCP or CGC HACCP.

Combined Audit - an audit where the scope includes more than one program, e.g. CIPRS+ HACCP and ISO 9001:2008

Document Review – assessment of a company's documentation to ascertain conformance with the CGC FSIP-STAN 1.1.0.

Implementation Audit – the first complete on-site audit to determine conformance of a company's management system with the requirements of CGC FSIP-STAN 1.1.0.

Pre-Assessment – on-site audit (gap analysis) conducted to determine if the management system meets the requirements of the CGC FSIP-STAN 1.1.0. This is discretionary and its necessity determined between the client and the ASP.

Prerequisite Programs (also known as Good Operating Practices or Good Manufacturing Practices) – procedures designed to control hazards related to personnel and the environment, creating conditions that are favourable to the production of a safe product.

Special Visit – an on-site audit conducted by the ASP at the request of the PVA.

> **System Audit** – complete on-site audit conducted annually to ensure continued conformance of the company's management system with the requirements of CGC FSIP-STAN 1.1.0.

2.0   SERVICE AGREEMENT WITH THE CLIENT

The client can use the services of the ASP of their choice. It is the responsibility of the chosen ASP to enter into an agreement with the client for the three-year duration of the certification.

3.0   AUDITS

The objectives of the audit are to:
- determine that the client's management system meets the requirements of FSIP- STAN 1.1.0;
- determine that the client's documentation accurately describes the procedures that are followed on a day-to-day basis by the facility;
- determine that personnel have received the appropriate training and conduct activities according to procedure;
- offer the company an opportunity to improve by observing and citing opportunities for improvement; and
- serve as an effective management tool to enhance a company's existing management system.

In addition, the objective of a CIPRS audit is to demonstrate traceability and compliance with the contracting requirements for production.

In addition, the objective of a HACCP audit is to determine that the generic prerequisite programs (where used) and generic HACCP model have been adapted and implemented appropriately to the facility. The duration of a CGC HACCP or CIPRS+HACCP system audit, including document review and on-site assessment, must take, at a minimum, one (1) day.

3.1   Audit Purpose and Scheduling

3.1.1   Pre-Assessment

The purpose of a pre-assessment is to provide the client with an initial evaluation of their management system relative to the requirements of the CGC FSIP-STAN 1.1.0. This type of gap analysis is helpful for a client preparing for a document review and implementation audit. Whether a pre-assessment takes place, as well as what the scope and approach of the pre-assessment will be, is left to the discretion of the ASP and the client. Items to be covered must be discussed and contractually agreed upon by the client.

3.1.2   Document Review

Before conducting an on-site audit, the client's documented management system shall be reviewed by the ASP auditor to verify that it meets the requirements of the CGC FSIP-STAN 1.1.0. The auditor will confirm that:

- top management has approved the management system and accepted responsibility for the process;
- the system's documentation is current;
- the company has a process to evaluate suppliers of services and products;
- the company has a process to determine and review customer requirements;
- the company has a system to analyse the cause of non-conformances and take corrective and preventive actions;
- the company has trained personnel conducting activities that impact on product; and
- the determination of sampling for multi-site auditing is appropriate, if applicable (see Multi-Site Auditing, Appendix VI).

Where necessary, the auditor will issue a CAR if changes are needed to the documentation. CARs will be issued until the auditor determines that the documentation meets the requirements of CGC FSIP-STAN 1.1.0 and the on-site audit can proceed.

The document review will confirm that:

- the documented prerequisite programs describe how the facility will achieve the requirements of CGC FSIP-STAN 1.1.0, Annex 3
- a complete HACCP plan is presented, including:

   o   a product description;
   o   a list of ingredients and incoming materials;
   o   the process flow diagram for the facility;
   o   a facility schematic;
   o   a summary of the hazard description and CCP identification (where applicable);
   o   a list of uncontrolled hazards; and
   o   the critical limit and monitoring, deviation, corrective action and verification procedure for CCP(s) (where applicable)

3.1.3 Implementation Audit

The implementation audit is the first on-site audit of the client's food safety and/or IP management system. It shall not be scheduled until the document review has been completed and all issues have been resolved. In an implementation audit, the entire food safety and/or IP management system must be assessed including the conduct of a traceability exercise as described in Appendix 1.

3.1.4 Annual System Audit

Full system audits must be conducted annually within 60 days of the anniversary date of the company's certification. The PVA will advise the company of the requirement for an annual system audit at least 60 days before the anniversary date. It is the responsibility of the company to ensure that the audit is conducted within those 60 days. Exceptions or requests for extensions must be submitted in writing to and approved by the PVA.

In preparation for an audit, the auditor reviews information from the previous audit, non-conformances, opportunities for improvement and Corrective Action Requests (CARs). Company information should also be confirmed, using the Company Information Sheet (Appendix V).

In an annual system audit, the entire food safety and/or IP management system must be assessed, including the conduct of two or more traceability exercises as described in Appendix 1.

3.1.5 Special Visit

A special visit is an on-site audit conducted by the ASP at the request of the PVA, typically in response to a complaint made to the CGC by a buyer sourcing product from a CGC-certified company, or in response to complaints or information from other sources. A special visit will be requested only if the buyer is unable to resolve the issue directly with the company.

3.1.6 Multi-Site Audits

If a client has more than one facility included within its scope of certification, audits will be conducted annually at headquarters and at the remaining sites as outlined in Appendix VI. Auditors must ensure that audits at Head Office include confirmation of internal audits at remote sites, where those sites will not have an on-site audit conducted there as part of the sampling.

4.0   PREPARATION FOR AN ON-SITE AUDIT

4.1   Audit Teams

The composition and size of the audit team will vary depending on the size and complexity of the facility/operation being audited, and the scope of the audit. A Lead Auditor must be designated for each on-site audit.

The Lead Auditor determines the appropriate size and composition of the audit team and appoints additional auditors and technical experts accordingly. The

Lead Auditor shall verify that each individual of the audit team has the necessary qualifications to address the scope and requirements of the planned audit.

4.1.1 Impartiality and Objectivity

Confidence in the audit depends on the known and perceived independence of the auditor(s) from the facility. Where there is an existing relationship between the client and the auditor, pre-approval is needed from the PVA. Auditors who have provided consulting services to a client within the past two years cannot provide audit services to that same client.

4.1.2 Responsibilities

All auditors on the audit team are responsible for becoming familiar with:

- this audit procedure and all associated documentation; and
- the client's organization, food safety and/or IP documentation, operating procedures, and health and safety requirements, including any requirements for the wearing of safety footwear/headwear.

The Lead Auditor has the following additional responsibilities:

- acting as a liaison with the company and other audit team members (which may include technical experts);
- ensuring that all operations described in the documentation are adequately covered in the audit; and
- determining the date and duration of the on-site audit, in conjunction with the client; and planning, arranging, conducting and reporting on the audit and any follow-up actions.

> **The Lead Auditor shall ensure that the prerequisite programs and the HACCP Plan are audited.**

4.2 Observers

When observers are part of the audit team, they must:

- have been previously approved by the client;
- accompany the Lead Auditor during the entire audit;
- address comments only to the Lead Auditor; and
- remain with their assigned group.

4.3 Pre-Audit Team Meeting

On audits requiring an audit team, a pre-audit team meeting shall take place before the opening meeting with the client. At the pre-audit team meeting, the Lead Auditor ensures that all information on the audit procedures and policies, timetables, etc., have been provided to the team members and understood by them.

The audit team members must be made fully aware of the areas of the on-site audit they are to cover. If there are any observers participating in the on-site audit, their responsibilities should be clearly defined and understood by the team members and the client.

4.4   Checklists and Audit Notes

Checklists are an optional tool and provide a reference to ensure that all elements of the standard and the company's processes are covered in an audit. They may also be used to record objective evidence of the auditor's findings and recommendations.

Auditors are to retain any checklists and/or their audit notes on their client file for a minimum of five years from the date of the audit. These client files may be called into the PVA for review as part of the ASP monitoring process (see CGC QSP 2.1.0 Accreditation and Monitoring of CGC Service Providers).

A sample CIPRS checklist is available. If a checklist is used when auditing a soybean exporting company's IP system, it should be revised to ensure that the additional Soy Canada requirements (CGC FSIP STAN 1.1.0, Annex 1) are included.

A sample CGC HACCP checklist is available. When auditing a CIPRS+ HACCP program, both the CIPRS and the CGC HACCP checklist are appropriate.

5.0   ON-SITE AUDIT

During an on-site audit, witnessing the client's processes, observing activities and facility conditions, conducting interviews, and examining documents provide objective evidence that processes are being implemented as described in the client's documented management system. The Lead Auditor shall obtain and document evidence to demonstrate that:

- the client's documentation is accessible, of correct issue, and available to all staff;
- the procedures described in the client's manual are being adhered to;
- the processes are being performed by competent personnel according to specifications stipulated in the relevant procedures; and
- the personnel are competent in the tasks they are performing.

The lead auditor shall obtain and document evidence that demonstrates that the food safety system is effective by verifying that:
- the procedures, prerequisite programs, monitoring and verification activities described in the client's documentation are being adhered to; and
- the generic prerequisite programs (where applicable) and generic HACCP model have been adapted and implemented appropriately at the facility.

5.1   Opening Meeting

An opening meeting is held with the client's senior management. The Quality System Representative and/or Food Safety Team Leader, senior management, and the audit team should attend this meeting. A List of Audit Participants (Appendix II) must be completed.

The objective of the opening meeting is to:

- introduce the members of the audit team;

- describe the purpose and scope of the audit;

- explain sampling of records;

- define non-conformances and review with the client the method for handling any non-conformances that may appear during the on-site audit;

- arrange for escorts, when necessary, to accompany the auditors during the on-site audit;

- arrange for suitable facilities for the audit team meeting;

- agree on a tentative time for the closing meeting, and invite senior management to attend;

- confirm with the client that the audit and any information gained during the audit will remain confidential; and

- arrange a familiarization tour (if necessary) of the facility prior to the on-site audit.

5.2   Audit Methodology

The auditor(s) will conduct the audit by:

- interviewing key employees;

- observing activities and facility conditions;

- collecting sequential evidence of traceability by tracing an appropriate sample of lots (see Appendix I);

- evaluating the core business processes of the company.

The name and position of all employees interviewed will be recorded on the sample List of Audit Participants (Appendix II).

The corrective actions that were implemented by the client in response to the non-conformances identified during the document review must be verified during the on-site audit.

CIPRS+ HACCP and CGC HACCP are HACCP-based programs, meaning that they are based on a generic hazard analysis for grain handling that was carried out following the Codex Alimentarius seven principles of food hygiene. The hazard analysis was carried out by teams of grain industry and government technical experts and has been translated into a series of generic prerequisite programs (called Good Operating Practices or GOPs) and a generic HACCP plan. A pre-developed HACCP plan and generic prerequisite programs provide grain handling companies with information on risks and hazards pertinent to their operations, reducing the levels of scientific knowledge and judgement required. However, it

is critical that the company correctly tailors and adapts the generic HACCP plan and generic prerequisite programs to the specifics of its operations.

The CGC established a Technical Expert Advisory Committee on HACCP (TEAC Committee) made up of CGC grain safety and industry experts that guided the development of the generic HACCP plan. Therefore, when auditing a HACCP-based program, the auditor is not required to assess whether the hazard analysis was conducted correctly and is supported by appropriate scientific information. Instead, the role of the auditor is to assess whether the generic HACCP plan and generic prerequisite programs are appropriately implemented in the facility being audited.

Some companies will have a pre-existing HACCP system in place or will choose to develop their own prerequisite programs rather than use the generic GOPs. In these instances, auditors must assess the company-specific prerequisite programs to verify that the outcomes required by the CGC FSIP STAN 1.1.0, Annex 3 are achieved.

Similarly, those companies with pre-existing HACCP systems will have already conducted a hazard analysis and developed a HACCP Plan. In these instances, auditors must verify that the company HACCP Plan accurately reflects the facility's products, incoming materials, processes, operations and physical infrastructure.

5.2.1 Auditing Prerequisite Programs

If the generic GOPs are used, auditors must verify that they have been adapted appropriately to reflect the facility's particular operations. This must include verifying that the procedures in the generic GOPs accurately describe the procedures as they occur in the facility or that they have been adapted to reflect the facilities' operations without compromising the required food safety outcome.

Whether the generic GOPs are used, auditors must review each prerequisite program to ensure that it is being followed as documented. The practices of the staff must be consistent with the procedures and the records generated must represent the work they are doing and how they respond to problems. This review should include interviews with the supervisors and staff of each department to assess their understanding of the programs and their commitment to them. Auditors must ensure that the monitoring of the prerequisite programs has been verified and a record of the verification maintained.

Auditors should ensure that the hazards identified in the company's HACCP Plan as controlled by a prerequisite program are included in the written prerequisite program, along with the actions that are taken to control it.

5.2.2	**Auditing the HACCP plan** The facility's HACCP Plan must be reviewed to verify that it accurately reflects the facility's products, incoming materials, processes, operations and physical infrastructure. The monitoring, deviation, corrective action and verification procedures for any CCP(s) identified must be verified through observation, interviews with staff and a review of records.
5.2.2.1	**Processes not included in the Generic Model.** In most cases, the generic model will be adapted with little change. However there may be instances where the company wishes to include a process or has an input that has not been reflected in the generic model. If this occurs, the auditor should indicate that the particular process(es) will be excluded from the audit, but collect all the objective evidence to submit to the PVA for review by the TEAC committee. This objective evidence must include: • a description of any additional processes including the type of equipment used and the purpose of the process; • a description of any additional inputs including the purpose and how they will be used; and • the identification and analysis of the hazards related to the additional input(s) or process(es) The PVA will present this information to the TEAC committee in a manner that maintains the anonymity of the company. The TEAC will determine if the generic model should be revised to incorporate the additional input(s) or process(es). Revisions made by the CGC will be communicated to the company, ASPs and other clients by the PVA.
5.2.2.2	**CCP Identification** Companies may choose to identify CCPs that they deem necessary to meet customer requirements or better control hazards within their unique operation. The auditor is not required to assess whether the hazard analysis and CCP identification was conducted correctly and is supported by appropriate scientific information. Instead, the role of the auditor is to assess whether the generic HACCP plan is appropriately implemented in the facility being audited. The monitoring, deviation, corrective action and verification procedures for any CCP(s) must be verified by the auditor through observation, interviews with staff and a review of records.

5.2.3	**Revisions to the Generic HACCP Plan**
	The TEAC committee is responsible for an annual review of the generic HACCP plan. Any changes are made to the generic HACCP plan resulting from this review will be provided by the PVA to all ASPs and CIPRS+ HACCP and CGC HACCP clients. Companies certified under CIPRS+ HACCP and CGC HACCP are required to implement the revisions within one (1) year of the release of the revised CGC generic HACCP plan. ASP auditors must verify that the revisions are implemented appropriately for the facility during the next audit.
5.2.4	**Legal Requirements Policy**
	The auditor must confirm that the company has a policy statement that commits it to observing all applicable food safety and sanitation legal requirements; a method for identifying all applicable laws pertaining to food safety and sanitation; and a method for keeping current with changes in food safety and sanitation legal requirements. If, during the course of the on-site audit, the auditor finds or suspects that the company is not in compliance with their legal requirements for food safety and sanitation, the auditor will indicate that a major non-conformance has been found and will follow the procedure outlined in Section 6.3.
5.2.5	**Objective Evidence**
	Auditors are to keep notes regarding the audit, documenting records that have been reviewed, information for corrective action requests, opportunities for improvement and positive comments. Evidence documented in auditor notes must be sufficient for the auditor to defend his/her findings and to judge to what degree the system is in compliance. Where requirements have not been met, the auditor must clearly outline which requirements were not met and how.

6.0   NON-CONFORMANCES

A non-conformance is found if the audit team members identify a gap that clearly does not meet the requirements of the FSIP standard or the client's documented food safety and/or quality management system. All non-conformances must be recorded, and a Corrective Action Request (CAR) Form (Appendix III) must be completed. However, prior to writing a CAR, and before the closing meeting, the client should be informed of the gap and provided an opportunity to respond and if possible, immediately identify corrective and preventive actions.

6.1   Classification of Non-Conformances

Non-conformances must be classified using the following guidelines:

Classification	Description	Examples
Observation	A single observed lapse or isolated incident that does not present a product risk. Three or more observations within one program element may result in the observation being elevated to a minor.	An unsigned or un-initialed prerequisite program checklist.
Minor Non-conformance	Failure to conform to a requirement that is not likely to result in system failure or contamination of product. Minor non-conformances have little likelihood of allowing nonconforming or contaminated product to be delivered or of causing a breakdown in the FSQMS. They indicate occasional lapses that must be addressed through corrective action. Three or more minor non-conformances in several areas within one element could indicate that the entire element has not been well implemented, maintained or effective. If it is clear that the element is functioning poorly, the minor non-conformances should be combined into one major non-conformance.	An excessive build-up of dust and cobwebs observed in the processing area. An opening has been left unsealed. Sprouted spilled grain found in the receiving pit area.
Major Non-conformance	A total breakdown of system, control, or procedure that could have a significant adverse effect on food safety or on the usability of the product for its intended purpose. Requirements of the standard are not met and potential hazards are likely to occur.	Product shipped without required inspection and/or tests. Critical purchases made from unevaluated suppliers. Internal audits not being conducted on an annual basis.
Classification	Description	Examples
Critical	Product contamination or food safety hazards are observed or the product has been knowingly contaminated without appropriate disposition or corrective action. Immediate corrective actions are needed.	Lubricant is observed dripping into the product and no one can confirm that it is food-grade. Records show glass found in finished product and no record of corrective action.

6.2   Actions Required when Minor Non-Conformances are Found

The client is required to submit their corrective action plan with respect to minor non-conformances to the auditor **within 10 working days** of the audit, although some companies may be in a position to provide their corrective action plan when they sign the CAR at the closing meeting. The auditor shall accept the corrective action plan (if the actions are deemed appropriate) and submit the audit report, copies of CARs and accepted corrective action plans to the PVA as outlined in Section 7.3. A recommendation for certification may be submitted to the PVA by the auditor with open minor CARs, as long as the action plans have been received. Verification that corrective action has been implemented must be done during the next annual audit.

6.3   Actions Required when Major Non-Conformances are Found

6.3.1   During an implementation audit

If a major non-conformance is found during an implementation audit, the Lead Auditor is authorized to stop the audit and propose to the client two alternative actions:

- It may be changed to a pre-assessment. The audit will be completed, a report will be prepared for the client, but not submitted to the PVA, and an implementation audit may be rescheduled for a later date.

OR

- The audit may be completed and the audit report will indicate that a major non-conformance was found and recommend that no certification be granted. Certification will be deferred until the correction action has been taken and confirmed.

If the second option is chosen, the client is required to submit their corrective action plan with respect to a major non-conformance to the auditor within **5 working days** of the audit. The auditor shall accept the corrective action plan (if the actions are deemed appropriate) and submit the audit report, copies of CARs, and accepted corrective action plans to the PVA as outlined in section 7.3. The client is also responsible for implementing corrective actions, scheduling and undergoing a follow-up visit (if required) within **40 working days** of the auditor's acceptance of the corrective action plan.

After the follow-up visit, the auditor shall submit a report to the PVA verifying he or she has collected objective evidence that effective corrective action has been taken and certification may be granted.

If the client fails to implement corrective action and undergo a follow-up visit within **40 working days** of the auditor's acceptance of the corrective action plan, the certification will be denied and the certification process must be re-initiated by the client.

6.3.2   During an annual system audit

If a major non-conformance is found during an annual system audit, the auditor must advise the PVA in writing of the major CAR within **24 hours** of the audit.

The client is required to submit their corrective action plan with respect to a major non-conformance to the auditor within **5 working days** of the audit. The auditor will accept the corrective action plan if the actions are deemed appropriate. The client is also responsible for implementing corrective action, scheduling and undergoing a follow-up visit (if required) within **20 working days** of the auditor's acceptance of the corrective action plan.

After the follow-up visit or documentation review as required, the auditor shall submit the audit report, copies of CARs, and accepted corrective action plans to the PVA as outlined in section 7.3. The audit report must verify that he or she has collected objective evidence that effective corrective action has been taken.

If the client fails to take corrective action within **20 working days** of the auditor's acceptance of the corrective action plan, the client's certification will be withdrawn. The client has the right to appeal the withdrawal of their certification as described in section 6.5.

6.4 Actions Required when Critical Non-Conformances are Found

If a critical non-conformance is found during any audit, the auditor must advise the client that its certification is suspended effective immediately and that any contaminated product must be segregated. If there is an immediate threat to public health or safety, the auditor must advise the client to contact the PVA as soon as possible, but no later than 12 hours after the audit. If this advice is verbal, it must be confirmed in writing within 24 hours of the audit.

Once advised of the critical non-conformance, the PVA will provide the client with instruction on the disposition of any contaminated product. In addition, if the PVA believes there is a potential need for recall actions, it will contact the Canadian Food Inspection Agency (CFIA) to coordinate the recall.

The client must:

- take immediate corrective action to segregate any contaminated product and initiate a root cause analysis;

- dispose of any contaminated product as instructed by the PVA;

- inform the PVA and the auditor of the results of the root cause analysis and the resulting corrective action plan within **5 working days** of the audit; and

- implement corrective actions, schedule and undergo a follow-up visit to verify the implementation within **10 working days** of the auditor's acceptance of the corrective action plan.

After the follow-up visit, the auditor shall submit the audit report, copies of CARs, and accepted corrective action plans to the PVA as outlined in section 7.3. The audit report must verify that he or she has collected objective evidence that effective corrective action has been taken. The suspension will be lifted or the re-certification will be granted.

If the client fails to take corrective action within **10 working days** of the auditor's acceptance of the corrective action plan, the client's certification will not be granted or will be withdrawn.

6.5 Client Appeals of Certification Suspension

If a client disagrees with the Lead Auditor's recommendation for suspension, the client can appeal to the PVA in writing. Within 10 days of receiving a written appeal, the PVA will initiate the appeal process described in CGC QSP 1.1.0, Section 6. Auditor recommendations will be supported by the PVA at all times, unless an investigation indicates otherwise.

7.0 POST-AUDIT ACTIVITIES

7.1 Audit Team Meeting

Upon completion of the on-site audit, the audit team will meet to review the completed checklists and/or audit notes, including the noted non-conformances. The team decides which non-conformances merit a CAR, and completes the appropriate forms.

The Lead Auditor should consolidate any non-conformances which arise from different parts of the operation, but which all relate back to a common element of the CGC FSIP-STAN 1.1.0.

If the audit reveals areas of the system that could benefit from improvement, but were not out of compliance with the CGC FSIP-STAN 1.1.0, these may be brought forward to the client as recommendations, with the understanding that their implementation is optional.

The facility's Quality System Representative and/or Food Safety Team Leader should be fully informed of the on-site audit findings prior to the closing meeting.

7.2 Closing Meeting

The closing meeting is chaired by the Lead Auditor, and should include all audit team members, the food safety and/or Quality System Representative and the company's senior management. The List of Audit Participants (Appendix II) will be completed. During the meeting, the Lead Auditor should:

- present an objective overview of the on-site audit, including the objectives, the elements assessed and the results, starting with the positive aspects and any general observations;
- discuss any adverse findings from the on-site audit as detailed on the CARs;
- obtain signatures on any CARs raised and the Audit Report Lead Sheet (Appendix IV) and as an acknowledgement that the findings are understood by the facility;
- inform senior management of the timeframes for submission of corrective action plans and the intended issue date for the audit report;
- inform the client that a recommendation will or will not be forthcoming (which will be indicated on the lead sheet), but final certification is the decision of the PVA; and
- leave copies of the CARs with senior management.

7.3 Audit Report

As soon as possible after the completion of the on-site audit and once the corrective action plans have been received, the Lead Auditor prepares the audit report. The completed audit report, and required appendices, must be sent to the PVA **within 20 working days** of the closing meeting. The auditor keeps a copy of the entire report and provides a copy to the company.

7.3.1 Recommendations for Certification

If, as the result of the audit, the Lead Auditor determines that the food safety and/or IP quality management system has been effectively implemented or continues to be effective, a recommendation for certification or continued certification shall be made.

If the auditor finds a major or critical non-conformance during an implementation or annual system audit, he or she must not recommend the client for certification. Certification will be recommended by the auditor only after corrective action has been taken and verified through a follow-up visit.

7.3.2 Audit Report Format

The Audit Report Lead Sheet (Appendix IV or a cover sheet containing all the required information) must be completed in full and be the first page for each audit report. This should be followed by a brief narrative report that covers the following topics, as appropriate for the type of certification:

- duration of the audit;
- limitations of an audit and the auditor's limitation of liability;
- strengths of the company's system;
- opportunities for improvement;
- summary of Corrective Action Requests;
- confirmation of traceability audit conducted on an appropriate sample of lots stating start/end evidence viewed (for CIPRS and CIPRS+ HACCP only);
- confirmation that a document review has been completed, including confirmation that the written prerequisite programs have been assessed against the FSIP Standard;
- confirmation that the prerequisite programs are implemented and activities conducted as documented
- confirmation that the HACCP Plan was assessed against the generic model;
- description of any CCPs identified in the company's HACCP Plan and confirmation that CCP monitoring has been verified; and
- certification recommendation.

If the audit report reflects the results of a combined audit, it should be clear which of the findings described refer to the CGC programs.

In addition, the following documents should be submitted to the PVA with the audit report:

- A completed List of Audit Participants (sample Appendix II);
- A signed Company Information Sheet (sample Appendix V);
- Copies of completed CAR forms (Appendix III) for all CARs issued;

- A copy of the company's HACCP Plan if additional processes or inputs have been included for review by the TEAC to determine if the generic model will be revised (see Section 5.2.2.1).

7.3.3 Objective evidence to be kept on file by auditors

It is the responsibility of the auditors to retain their checklists and auditor notes as objective evidence on file for a minimum of five years after the date of the audit. Auditor files may be subject to review by the PVA as part of its monitoring of ASPs (CGC QSP 2.1.0 Accreditation and Monitoring of CGC's Accredited Service Providers).

8.0 CONTINUING RESPONSIBILITIES

8.1 CGC Clients

8.1.1
Clients who have been successful in obtaining certification of their food safety and/or IP programs shall:

- demonstrate their commitment to ensuring the continued effectiveness of their food safety and/or IP system;

- ensure that an annual system audit is conducted, as part of the ongoing audit program agreement with their chosen ASP;

- afford ASP auditors such reasonable co-operation as is necessary for the purpose of audits;

- continue to adhere to their food safety/quality system;

- maintain complete and accurate records as specified by their quality manual; and

- participate in the ongoing audit program as described in Section 3.1.4 of this QSP.

8.1.2 Recertification

Clients must be re-certified every three (3) years. The PVA will remind the company of the expiration of the certification agreement in writing six (6) months and one (1) month prior to the end of the certification period.

If the company does not schedule an annual system audit within 60 days of the expiration of the certification agreement, the company's certification will be deemed to have expired. The CGC will notify the company and the ASP that certification has expired, the company name will be removed from the CGC web site, use of load certificates will be revoked, and the company will be prohibited from representing itself as a CGC-certified company. Exceptions or requests for extensions must be submitted in writing to and approved by the PVA.

8.2   PVA

The PVA is responsible for:

- maintaining CGC FSIP STAN 1.1.0 and advising all clients and ASPs of changes to the standard;

- maintaining a list of ASPs and making it available to all CIPRS+ HACCP clients or potential clients;

- maintaining a database on the client that includes information on dates of certification, audits and other information essential to the operation of the CIPRS+ HACCP; and

- advising clients when they are due for annual system audits.

8.3   ASPs and ASP Auditors

The ASPs and ASP auditors are responsible for:

- advising the PVA when audits are scheduled;

- ensuring that an annual system audit is conducted, as part of the ongoing audit program agreement with the client company; and

- objective evidence as required under section 7.3.3.

APPENDIX I – Conducting a Traceability Audit

The purpose of conducting a traceability audit is to verify that traceability is possible through a review of the client's records. The following process flow and description outlines the records the auditor should be reviewing to verify traceability.

PROCESS STEPS	POTENTIAL RECORDS TO REVIEW
SHIPPING	• Carrier inspection • Lot number identification on outbound product / source bin • Shipping documentation
⬇	
FINISHED PRODUCT STORAGE	• Grain lot number identification • Bin inspection and bin/warehouse identification
⬇	
PROCESSING/HANDLING	• Source bin identification • Processing records • Product and lot number identification
⬇	
STORAGE	• Grain lot number identification • Bin inspection and identification
⬇	
RECEIVING	• Producer and grain lot number identification • Inspection records • Transport affidavits
⬇	
TRANSPORTATION	• Grain lot number identification • Carrier inspection
⬇	

↓		
ON-FARM STORAGE		• Bin inspection • Grain lot number identification
↓		
HARVESTING		• Equipment cleanliness • Field/harvesting records • Grain lot number identification
↓		
FIELD PREPARATION		• Field records • Pesticide application records
↓		
PLANTING		• Seed lot number identification • Field location • Previous/adjacent land use • Equipment cleanliness • Planting records
↓		
STORAGE		• Bin location and identification • Bin inspection for cleanliness • Seed lot number identification
↓		
RECEIVING SEED		• Certificate of analysis or certified seed tag • Seed lot number identification • Sample retention

The auditor must trace specific lot numbers through the system, starting with shipping records back to producers' records. Relevant records, dates, commodities, bin numbers, should be well referenced in the auditor's notes or checklist to provide objective evidence of traceability and a statement included in the audit report.

Auditors must follow the sampling plan below to determine the number of lots to trace at a particular facility, based on the amount of product shipped. Auditors are to follow this guide at annual system audits. If the auditor identifies gaps in one of the lots selected for traceability, he/she must trace another lot. If a gap in traceability is found in more than one lot, a major non-conformance shall be issued.

Number of Lots Shipped per Year	Sample Size (Number of lots to be randomly selected for traceability audit)
1-2	2
3-10	2
11-30	2
31-100	3
100 +	3

APPENDIX II – List of audit participants

Client name _____

			Opening meeting	Closing meeting	Interview
1	Name Title Department				
2	Name Title Department				
3	Name Title Department				
4	Name Title Department				
5	Name Title Department				
6	Name Title Department				
7	Name Title Department				
8	Name Title Department				
9	Name Title Department				

APPENDIX III – Corrective action request (CAR)

CAR No.: _____

Company under audit:	Audit date:
Activities under review:	

Audit criteria: (GOP, HACCP plan, QM, Standard):	Category of non-conformity: ☐ Minor ☐ Major ☐ Critical

Type of Audit:	Pre-assessment ☐ Certification ☐	Surveillance ☐ Recertification ☐

Requirement (standard clause no., procedure no.):

Non-conformity:
Corrective action plan (attach separately if necessary):
Date correction to be completed:

Accepted: _____ *(Auditor initial)*

Action taken:

Auditor's name:	Signature:
Client representative's name:	Signature:

Verification of corrective and preventative action taken:	
Signature: _____ *Auditor*	Date: _____
Signature: _____ *Client Representative*	Date: _____

APPENDIX IV – Audit report lead sheet

Date of document review _____   Previous audit date _____

Date of audit _____   Duration of audit   _____

Type of audit _____   Audit criteria: _____(Rev. #)

Company assessed _____

Address _____   Email address _____

Telephone number _____   Fax number   _____

Audit team
Lead auditor   Team members   Observers

_____   _____   _____

                                 _____   _____

                                 _____   _____

Program recommended for certification, continued certification or recertification

☐   Yes   ☐   No

Number of Corrective Action Requests issued

Major [#]_____   Minor [#] _____   Critical (#) _____

Outstanding Corrective Action Requests from previous audit closed   ☐   Yes   ☐   No

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By signing this document, I hereby certify that all of the information on this lead sheet is correct.

Signature_____   Signature _____
                Lead auditor   *Client representative*

Date_____   Date _____

APPENDIX V – Company Information Sheet

Full company name _____

Address _____

_____

Full contact name _____

Telephone number _____   Fax number _____

E-mail address _____

Number of employees _____   Multi-site   ☐ Yes   ☐ No

Scope

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____   _____

Client approval   *Date*

APPENDIX VI – Multi-Site Auditing

Introduction

This appendix provides instruction to auditors on the sampling requirements for multi-site facilities.

The definition of a multi-site organization is an organization having an identified central function at which certain activities are planned, controlled or managed and a network of sites at which such activities are fully or partially carried out. The organization's quality management system is centrally administered under a centrally controlled plan and subject to central management review including internal and external audits for facilities identified in the organization's scope.

Eligibility Criteria

When auditing organizations with multiple sites, the goal is to verify that the quality management system conforms to the standard, while maintaining the economic and operational feasibility.

The processes used at multi-sites must be substantially the same and conducted fundamentally according to the same methods and procedures. The ASP must conduct a document review prior to assessment to verify the similarities between sites and determine the complexity and scale of the activities covered by the QMS. Factors to be taken into consideration may include:

- diversity of activities/processes
- diversity of crop types processed
- diversity of size of facilities (e.g. high throughput facility vs. small dedicated facility)
- differences in regulatory requirements (e.g. provincial)

Dealing with Non-Conformances

If any non-conformances are found at an individual site (either through internal or external audit), an investigation should take place to determine whether other sites may be affected. If they are, corrective action (both centrally and at the site(s)) should be performed and evidence provided to the audit team. The team must be satisfied that control is re-established and may increase its sampling until it is assured of that.

Sampling Methodology

If a company has twenty (20) or fewer sites under the scope of the certification, all sites must be audited over the three-year certification period, with a minimum of 33% of all sites being audited each year.

If a company has more than twenty (20) sites under the scope of the certification, then sites in excess of the first twenty (20) shall be randomly sampled at a ratio of one (1) site per five (5) sites. All sites shall be randomly selected. In order for the company to receive CIPRS, CGC HACCP or CIPRS + HACCP certification, all sites must meet the requirements of *CGC FSIP STAN 1.1.0 – Canadian Grain Commission Food Safety Identity Preserved Quality Management System Standard* and be eligible for certification.

The selection does not have to be done at the start of the audit, but may be done once the central office audit is completed. The central office will be notified of the sites to be part of the sample, with sufficient notice to prepare. The central office will be audited during every system audit.

Sampling size will be increased where the risk analysis of the activity/facility indicates special circumstances in respect of factors such as:

- the size of the sites and number of employees
- the complexity of the activity and of the QMS
- variations in working practices
- variations in activities undertaken
- records of complaints and other aspects of corrective and preventive action
- any multinational aspects
- results of internal audits.

Additional Sites

On the application of a new group of sites to join an already certified multi-site network, each new group of sites will be considered as an independent set for the determination of the sample size. After inclusion of the new group in the certification, the new sites will be cumulated to the previous ones for determining the sample size for future system audits.

Receiving Sites

Sites not included in the company's scope and that are solely designated as receiving sites (e.g. no grain handling or processing occurs at these sites) are exempt from external auditing and therefore should not be included in the multi-site sampling calculation. It is the responsibility of the certified company to perform internal audits on receiving sites to ensure they remain compliant to CGC FSIP STAN 1.1.0.

APPENDIX VII – Reduced CGC HACCP Audit Model

Introduction

This appendix provides instruction to auditors on the reduced CGC HACCP audit requirements for companies that hold HACCP-based food safety certifications with other certification bodies.

The purpose of the reduced CGC HACCP audit model is to lessen the redundancy of food safety audits while ensuring that the Canadian Grain Commission (CGC) Process Verification and Accreditation Office (PVA) has undertaken the due diligence necessary to verify that CIPRS+ HACCP requirements are met.

Eligibility Criteria

HACCP-based food safety system certifications eligible for the reduced audit model must be deemed equivalent to the CGC HACCP program. Companies that have a current certification to a Global Food Safety Initiative (GFSI)-benchmarked standard in good standing are eligible for a reduced audit schedule. Other food safety certifications will be considered on a case-by-case basis by the PVA.

Reduced Audit Procedure

1. For the first year, a full CGC HACCP audit shall be conducted by a CGC-accredited auditor. Prior to the CGC audit, the company shall submit its most recent audit report from the CGC-recognized food safety certification to the PVA. Once the auditor submits the audit report to the PVA, the CGC HACCP Technical Advisor will compare the CGC audit findings to the CGC-recognized standard audit report. If the findings of the CGC HACCP component of the audit are comparable to the CGC-recognized standard audit findings, then the PVA will permit a reduced audit program model based on continued compliance with the CGC-recognized standard requirements. If there are discrepancies between the CGC HACCP audit findings and the CGC-recognized standard audit report that could potentially result in grain being exposed to food safety hazards, a reduced audit program will not be permitted and the company will be subject to annual CGC HACCP audits.

2. If a reduced audit program model is accepted by the PVA, the company will be exempt from CGC HACCP annual system audits during the second and third year of certification. Companies that hold CIPRS+ HACCP certification will be subject to an audit of CIPRS-specific elements during the second and third years of certification and an audit report must be submitted to the CGC for a technical review. To ensure continued conformance to CGC HACCP requirements and continued certification to a CGC-recognized food safety standard, the company must submit the annual CGC-recognized audit report to the PVA within twenty (20) working days of receiving the audit report.

3. During the recertification year (the fourth year), the company must undergo a full CGC HACCP audit conducted by a CGC-accredited auditor. This audit will be conducted in the same manner as the initial CGC audit and the CGC HACCP Technical Advisor will compare the CGC audit findings with the most current CGC-recognized standard audit report, submitted by the certified company, to ensure that the most current CGC generic HACCP plan is being correctly applied to the company's

operations. Continued annual CIPRS audits would be required by a CGC-accredited auditor for companies that are CIPRS+ HACCP certified.

Additional CIPRS+ HACCP Requirements

Companies that hold a CIPRS+ HACCP certification must ensure that additional identity preservation standard requirements are met to maintain CIPRS certification. The additional CIPRS+ HACCP requirements that are not included in other food safety standard audits and must be audited in full annually as per *CGC QSP 2.3.1 Conducting a Food Safety/IP Quality Management System Audit*.

CIPRS Requirements

- 3.1.2 Documentation Requirements: General Requirements
- 3.3.4 Records
- 4.2.1 Customer Focus
- 4.6.2 Responsibility, Authority and Communication
- 5.2.3 Employee Training and Records
- 6.7.4 Customer Related Processes
- 6.9.3 to 6.9.9 Production and Service Provision
- 6.10.2 Identification and Traceability
- 6.13 Identifying CIPRS-certified shipments
- 7.5.2 Control of Non-conformances
- 7.8.2 Preventive Action

CIPRS+ HACCP Requirements

- 6.13 Identifying CIPRS-certified shipment
- Correct application of the generic CGC HACCP plan to the company's operations